OIPE IAP47 JAN 09 2006 PATENT & TRADEMARK OFFICE

Claim Amendments:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. – 39. (canceled).

40. (currently amended) A method for determining the concentration of at least one target constituent contained within biological fluid, the method comprising the steps of:

providing at least one micro-needle comprising an open distal end and a lumen;

providing an electrochemical cell within the lumen, the electrochemical cell comprising ~~a concentrically layered electrode configuration~~ an outer electrode and an inner electrode, wherein the electrodes each have a cylindrical configuration and are spaced from each other in a co-axial relationship, the micro-needle formed at least partially by the outer electrode;

inserting the open distal end of the micro-needle into the skin to a selected depth;

transferring a sample of at least one target constituent within the biological fluid present at the open distal end through the lumen and into the electrochemical cell;

providing a first electrical signal to the electrochemical cell; and

receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration of the constituent in the biological fluid.

41. (canceled)

42. (currently amended) A method for determining the concentration of at least one target constituent contained within biological fluid, the method comprising the steps of:

providing at least one hollow micro-needle comprising an open distal end, an open proximal end and a lumen extending there between;

providing an electrochemical cell in fluid communication with the hollow micro-needle, the cell comprising a parallely-spaced electrode configuration, wherein the

electrode configuration is positioned at the open proximal end of the hollow micro-needle substantially transverse to the micro-needle;

inserting the open distal end of the hollow micro-needle into the skin to a selected depth;

transferring a sample of the at least one targeted biological fluid constituent present at the open distal end of the hollow micro-needle into the electrochemical cell;

providing a first electrical signal to the electrochemical cell; and

receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration of the constituent in the biological fluid.

43. (currently amended) A method according to claim ~~40 or 41~~ 42, wherein the selected depth is no greater than the viable epidermis.

44. (original) The method according to claim 43 wherein the selected depth is no greater than the stratum corneum.

45. (currently amended) A method according to claim ~~40 or 41~~ 42 wherein the step of transferring comprises providing a hydrophilic gel material within the micro-needle lumen and in contact with the electrochemical cell, wherein the hydrophilic gel material absorbs at least one target constituent within biological fluid present at the open distal end of the micro-needle.

46. (currently amended) A method according to claim ~~40 or 41~~ 42 wherein the steps of providing a first electrical signal and receiving a second electrical signal is performed by a control unit in electrical communication with the electrochemical cell.

47. (currently amended) A method according to claim ~~40 or 41~~ 42 further comprising the step of deriving the concentration of the constituent in the patient's biological fluid from the second electrical signal.

48. (original) The method according to claim 47 further comprising the step of displaying a numerical value representative of the concentration of the constituent in the patient's biological fluid.

49. (original) The method according to claim 47 wherein the step of deriving comprises using a software algorithm.

50. (original) The method of claim 45 further comprising the step of allowing the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the at least one targeted constituent within biological fluid in the patient's skin prior to the step of providing a first electrical signal to the electrochemical cell.

51. (original) The method of claim 45 wherein the step of providing a first electrical signal to the electrochemical cell is performed prior to the time it takes for the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the least one targeted constituent within biological fluid in the patient's skin.

52-57 (canceled).

58. (new) A method according to claim 40 wherein the selected depth is no greater than the viable epidermis.

59. (new) The method according to claim 58 wherein the selected depth is no greater than the stratum corneum.

60. (new) A method according to claim 40 wherein the step of transferring comprises providing a hydrophilic gel material within the micro-needle lumen and in contact with the electrochemical cell, wherein the hydrophilic gel material absorbs at

least one target constituent within biological fluid present at the open distal end of the micro-needle.

61. (new) A method according to claim 40 wherein the steps of providing a first electrical signal and receiving a second electrical signal is performed by a control unit in electrical communication with the electrochemical cell.

62. (new) A method according to claim 40 further comprising the step of deriving the concentration of the constituent in the patient's biological fluid from the second electrical signal.

63. (new) The method according to claim 62 further comprising the step of displaying a numerical value representative of the concentration of the constituent in the patient's biological fluid.

64. (new) The method according to claim 62 wherein the step of deriving comprises using a software algorithm.

65. (new) The method of claim 60 further comprising the step of allowing the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the at least one targeted constituent within biological fluid in the patient's skin prior to the step of providing a first electrical signal to the electrochemical cell.

66. (new) The method of claim 60 wherein the step of providing a first electrical signal to the electrochemical cell is performed prior to the time it takes for the concentration of the at least one targeted constituent in the hydrophilic gel material to equilibrate with the concentration of the least one targeted constituent within biological fluid in the patient's skin.